

DETAILED ACTION

1. Receipt of Applicants arguments/remarks filed 08/16/2011 is acknowledged.

The Examiner acknowledges the following:

Claims 13 and 15 have been amended.

Claims 17 and 18 are new.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/16/2011 has been entered.

INFORMATION DISCLOSURE STATEMENT

3. Information Disclosure Statement filed 08/16/2011 is acknowledged and has been reviewed.

WITHDRAWN REJECTIONS

4. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

NEW REJECTIONS

Claim Rejections- 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 11, 13, 15, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. “AQUACEL™ HYDROFIBRE™ DRESSING: THE NEXT STEP IN WOUND DRESSING TECHNOLOGY”.

Chen et al. “AQUACEL™ HYDROFIBRE™ DRESSING: THE NEXT STEP IN WOUND DRESSING TECHNOLOGY” (hereafter Chen et al.) teach a wound dressing comprising highly absorbent fibers that can absorb at least 25 g/g of deionized water, said highly absorbent fibers being selected from the group consisting of alginate, viscose, modified cellulose, polyester, polypropylene and co-polymers thereof, pectin, chitosan, hyaluronic acid fibers, other polysaccharide fibers and fibers derived from gums (Introduction on page 6 last paragraph, page 12-13- see the sections: Composition and manufacturing, Physical Properties, and Mode of Action page 14 Figure: 3a). It can be used on burns (see page 36-Is it safe to use on burns/donor sites?). Chen et al. teach that the dressing is applied to a wound and there is adherence. With regards to leaving the dressing in place for epithelial outgrowth and vertical wicking into the dressing to occur, Chen et al. teach vertical wicking. With regards to leaving until the dressing dries out,

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Chen et al. teaching the dressing can be left on up to 7 days. For wounds that have less exudate the dressing would inherently exhibit this property. The dressing taught in Chen et al. is removed after the wound had healed.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10, 11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlisle (U.S. Pat. No. 3,824,996) in view of Dyer et al. (U.S. Pat. No. 5,899,893) and further in view of Bernardin et al. (U.S. Pat. No. 5,124,197).

Carlisle ('996) teaches highly absorbent pressure dressings for wounds substantially constructed from cellulosic, fibrous material formed in thin layers and

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adapted to be applied and affixed to curved surfaces of the human body (see claims and Abstract).

According to Carlisle, the dressings have a finely porous, highly dense fibrous construction which provides the dual advantages of dispersing absorbed exudates to a low interlayer adhesion level, and preventing healing tissues from becoming entangled with the dressing's fibrous material (col. 3, lines 53-67). Carlisle teaches the significance of speed of absorption, direction of absorption and the length of wicking (col. 4, lines 1-14). The chart at column 4 demonstrates that the dressing of Carlisle absorbs fluid steadily and continuously (i.e., wicking) (see col. 4, lines 15-55).

Carlisle teaches that the dressing layer materials can absorb distilled water *vertically* against gravity continuously for more than 5 hours (see claim 4). Carlisle also teaches that the dressing, when affixed and held in place with retaining material, adapts to exert relatively even pressure on the wound surface which tends to improve the quality of the repair tissue formed during healing (claim 17).

The wound dressings can be applied to wounds, such as burns (col. 2, lines 63-67).

Suitable dressing materials taught includes hard and soft wood pulp (col. 5, lines 19-22) and fibrous dense cellulose materials (see claims 1, 5, 6, 18).

The particular method of treating an acute wound using a wound dressing and applying the wound dressing to the wound would be obvious in view of the disclosure of Carlisle. Carlisle clearly teaches highly absorbent pressure dressings for wounds, such as burns, constructed from cellulosic, fibrous material, whereby the dressings are applied and affixed to curved surfaces of the human body.

With regards to the amount of water (25 g/g) that can be absorbed in claims 13-15, Carlisle does not teach absorbing at least 25 g/g of deionized water. However, this limitation is a result-intended effect of the absorbent fibers and merely demonstrates the water-absorption capacity of the absorbent fibers. Moreover, note in particular that Carlisle vividly suggests and teaches highly absorbent dressings that are constructed from *cellulosic and fibrous materials* – the same materials used by Applicant. Thus, one of ordinary skill in the art would reasonably expect that the water-absorption capability of the absorbent fibers of Carlisle would be the same as the water-absorption capability of Applicant's fibrous materials, based on usage of the same components, absent a showing of evidence to the contrary.

In any event, **Dyer *et al.*** ('893) are relied upon for their teaching of absorbent articles, such as wound dressings, having a vertical wicking capability of at least about 30 g/g, more preferably at least about 40 g/g. Particularly preferred foam absorbents will wick at least about 45 g/g. The foam absorbents of the invention wick a high capacity of the test fluid to a particular height at equilibrium (see reference column 1, lines 11-19); (col. 2, line 45); (col. 7, lines 41-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the absorbent articles of Dyer *et al.* within the teachings of Carlisle. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Dyer *et al.* teach absorbent articles, particularly wound dressings and teach that their absorbent articles are able to wick at a high capacity at equilibrium, such as a vertical wicking capability of at least about 30 g/g, more preferably at least about 40 g/g and even at least about 45 g/g. The expected result

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would be a highly absorbent wound dressing that is beneficially used for the treatment of acute wounds.

Bernardin *et al.* ('197) are relied upon for the teaching of an absorbent web formed from inflated cellulose fibers whereby the web possesses improved vertical wicking properties (see col. 1, line 6 – col. 2, line 30); (col. 3, lines 16-28) and Abstract. The absorbent webs are suitable for use in forming absorbent products, such as dressings, incontinence products, feminine pads and the like (col. 6, lines 41-46). Suitable fibers used in the invention include natural fibers, such as wood fibers, cotton linters and cotton staple (col. 3, lines 46-58).

Bernardin *et al.* teach that as a general rule, the vertical wicking properties of a web will be considered improved when the web exhibits at least about a 20 percent increase in initial vertical wicking rate, vertical wicking capacity (at 15 or 30 minutes) or vertical fluid distribution (at a distance between nine and eighteen cm) when compared to a similar web (col. 4, lines 36-52).

Bernardin *et al.* teach that the improved vertical wicking properties of the webs allow fluid to be vertically wicked from one particular area of the web to another remote location on the web. The absorbent web is able to transport fluid from one location on the web to another location on the web, based on the improved vertical wicking properties (col. 7, lines 8-40).

It would have been obvious to incorporate the absorbent cellulose fibers that exhibit improved wicking properties within the highly absorbent pressure dressing of Carlisle. One of ordinary skill in the art would do so with a reasonable expectation of success because Bernardin *et al.* teach an absorbent web made of cellulosic fibers, for use

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in absorbent products such as dressings and teach that the vertical wicking properties allows the absorbent web to transport fluid from one location on the web to another location on the web, thus increasing the absorbent capacity of the absorbent web.

With regards to the claim limitation ‘leaving the dressing in place for epithelial outgrowth and vertical wicking into the dressing to occur’ recited in instant claim 13 and 15, the Examiner notes that this limitation does not impart patentable weight to the claims. The limitation is relative in terms of the time required in which epithelial outgrowth and/or vertical wicking occurs since the limitation fails to set forth any specific time or duration parameters that are required for epithelial outgrowth and vertical wicking to occur. Moreover, regarding the limitation of “vertical wicking”, the Examiner notes that this limitation does not impart a patentable distinction over the explicit teachings of the art. The prior art teaches absorbent webs formed from cellulose fibers, used in dressings, whereby the absorbent webs demonstrate improved vertical wicking properties (see Bernardin). No unexpected results have been observed which would occur as a result of the particular direction of wicking (perpendicular wicking of the instant invention versus lateral wicking of the art). The art is well aware of providing for absorbent products that demonstrate enhanced wicking capabilities. Given the teachings of Carlisle, Dyer *et al.* and Bernardin *et al.* delineated above, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

RESPONSE TO ARGUMENTS

7. Applicants' arguments filed 08/16/11 have been fully considered and persuasive in part.

Applicants argued Carlisle is concerned with pressure dressings and that "according to Carlisle, pressure dressings are fundamental in the preparation of wounds for skin grafting. Carlisle does not, therefore, consider his dressings as a substitute for a biological dressing, but rather as a preparation for it. Carlisle would not, therefore, motivate the person of ordinary skill in the art to use a fibrous dressing as a substitute for a biological dressing.

In response, the Examiner respectfully submits that Applicants' arguments have been considered, but were not found persuasive. Carlisle teaches highly absorbent pressure dressings for wounds substantially constructed from cellulosic, fibrous material formed in thin layers and adapted to be applied and affixed to curved surfaces of the human body (see claims and Abstract). The fact that Applicants' dressing can be used as a substitute for biological dressings does not provide for a patentable distinction over the wound dressings of the art. The wound dressings of Carlisle are formed of the same materials as that of Applicants' dressing and therefore, the particular use of the dressing fails to impart a patentable distinction over the dressing of Carlisle. Moreover, the highly absorbent pressure dressings of Carlisle are used to treat wounds and thus read on the method of treatment of acute wounds claimed by Applicant. Thus, the argument that Applicants use their dressings as a 'substitute for a biological dressing' does not distinguish over the art, which also recognizes methods of treating wounds by application of dressings to the wounds in order to treat such wounds.

Applicants argue that Carlisle teaches wood pulp and wood pulp is cellulose. This is not the same material used in Applicants' dressings.

In response, the Examiner respectfully submits that Applicants' arguments have been considered and are persuasive in part. The wood pulp or cellulose material disclosed by Carlisle amply reads on the "other polysaccharides" as recited in Applicants' claims. Note in particular, that instant claim 13, for instance, recites that "highly absorbent fibers that can absorb at least 25 g/g of deionized water" include "other polysaccharides". As such the wood pulp (i.e., cellulose) taught by Carlisle meets the requirement of a "other polysaccharides" as well as the "highly absorbent fibers that can absorb at least 25 g/g of deionized water" as recited in Applicants' claims. In addition, the behavioral properties of the wood pulp (cellulose) would also be the same, based on the same component, (cellulose) absent a showing of evidence to the contrary.

Applicants argued that "Carlisle does not suggest that the dressings be used in the manner of a biological dressing, and, as claimed herein, which is left in place in its entirety and undisturbed until the wound has healed"

In response, the Examiner respectfully submits that Applicants' arguments have been considered but are not persuasive. The claims are more generic in scope and do not require any specific time frame with regards to duration of application of the dressing. Moreover, Carlisle states that their wound dressing can be left on the skin for extended periods of time, such as two or more weeks (col. 3, lines 54-67). Furthermore, with regards to the argument Carlisle removes his dressing before healing is complete and is not left to dry out, Carlisle teaches highly absorbent wound dressing made of the same components (i.e. cellulose), which would exhibit the property of drying out when left in

place. The Examiner would like to point out that Carlisle dressing are capable of being left to where they dry out. Applicants have not recited any specific time frame the wound dressing would dry out. The amount of wound exudate varies depending on the wound. If there is less wound exudate the dressing is going to dry out faster. Regarding the wound dressing of Carlisle, the amount of wound exudate would also vary, just like Applicants'. In both cases, the wound dressing is removed once the wound is healed.

Applicants argued, that Applicants' dressing and method are highly unusual in that, when used in the treatment of acute wounds, the dressing adheres to the wound and forms a crust. "This type of behavior would usually only be seen with a biological dressing such as allograft, and it is a truly surprising discovery." Applicants argue the fact that the dressing adheres to the wound and acts like a biological dressing when it is not, is an unexpected result. Applicants believe that this is due to the modulation of the inflammatory response caused by the vertical wicking property of the dressing. The unexpected results of vertical wicking are also shown in the Examples.

These arguments were not found convincing. The prior art in combination recognizes and teaches wound dressings/absorbent web articles for the treatment of wounds whereby the dressings/webs possess improved vertical wicking properties - the same result sought herein by Applicants. Thus, it cannot be seen as to how the prior art would be so distinguished from the instant invention as to render the claims non-obvious. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use,

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new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Applicants argued, "Carlisle's dressings cannot be left in place for vertical wicking to occur as Carlisle's dressing does not permit vertical wicking." The rejection relies on Bernardin for teaching absorbent webs with vertical wicking properties. The wicking of Bernardin is perpendicular to the vertical wicking of Applicants' claims. In relation to the wound, this wicking is lateral not vertical. "Applicants' vertical wicking is with respect to the wound, that is, vertically out of the wound and into the dressing."

These arguments were not persuasive. No patentability is seen in the particular direction of wicking (perpendicular wicking of the instant invention versus lateral wicking of the art). The art is well aware of providing for absorbent products that demonstrate enhanced wicking capabilities. Moreover, the claim limitation of "for epithelial outgrowth and vertical wicking to occur" is a future-intended property or effect that the wound dressing would possess. Applicants have not shown that the prior art's dressings would not at all be capable of this intended property. In this instance, the prior art is well aware of the benefits and advantages that accrue as a result of vertical wicking (To evidence the concept that vertical wicking is known to be desirable, see US Patent 5,540,964 that teaches transportation of moisture via vertical wicking to provide a dry and comfortable dressing. Additionally, US Patent 5, 437,621 further evidences that vertical wicking in a medical dressing is known in the art to be desirable (col 3 line 33-61). The fact that Applicants have claimed vertical wicking into their dressing does not

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impart patentability over the prior art. For these reasons, the rejections of record have been maintained.

CORRESPONDENCE

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danah Al-awadi whose telephone number is (571) 270-7668. The examiner can normally be reached between 9:00 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DA/

Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner
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